

**REMARKS**

Claims 10-12 are being canceled without prejudice in this response.

Claims 1, 2, 9, 18, 19-20, 23, 25, 41, and 71-72 have been amended. Claims 1, 19, 20, 23, 25, 41, and 71-72 have been amended to specify that the "feed composition as a final mixture comprises about 0.025% to about 2% by weight of the marine animal product." Claim 2 has been amended to delete the reference to "a fish meal product." Claim 9 has been amended to add the phrase "or the fish oil derived from the fish meal product." Claim 18 has been amended to change its dependency and to replace "fish oil" with "marine animal product."

**I. Rejection of claims 1-3, 5, 12-13, 15-17, 19-20, 23, 25, 41, and 71-72 under 35 U.S.C. § 102(b).**

Claims 1-3, 5, 12-13, 15-17, 19-20, 23, 25, 41, and 71-72 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Fritsche et al. Claim 12 has been canceled without prejudice obviating the Examiner's rejection of this claim. The Examiner indicates that Fritsche et al. inherently anticipates these claims because, according to the Examiner, Fritsche et al. discloses a method of increasing the reproductive performance of female swine by feeding the swine a composition including fish oil in the feed composition where the effective amounts of the fish oil are 3.5% and 7%. Applicants respectfully traverse the Examiner's rejection. The invention of amended claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72 is not anticipated by Fritsche et al.

Frische et al. does not inherently anticipate claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72. Fritsche et al. does not describe "a method of increasing the reproductive performance of a female swine" by supplementing a feed composition with marine animal products as claimed in amended claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72. As stated in Fritsche et al. in reference to feeding the pregnant sows a diet

supplemented with lard (*i.e.*, control diet), menhaden fish oil, or a mixture of lard and menhaden fish oil, “the number of live pigs born per litter . . . pig birth weights . . . did not differ among treatment groups” (page 1843, column 1, paragraph 2) and that affect on weaning weights was not significant. . Thus, Fritsche et al. teaches that administering to pregnant sows a feed composition supplemented with 3.5% or 7% by weight of menhaden fish oil does not increase the weight of or number of live pigs born per litter and wouldn’t be shown to affect weaning weights. Rather Frische is limited to use as altering an immune function and incidences of inflammatory disease (pg. 1846 bottom col. 1). Therefore, Fritsche et al. cannot inherently anticipate “a method of increasing the reproductive performance of a female swine” as claimed in claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72.

Moreover, claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72 have been amended. Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claims 1, 19, 20, 23, 25, 41, and 71-72, and their dependent claims 2-3, 5, 13, and 15-17, have been amended to specify that the “feed composition as a final mixture comprises about 0.025% to about 2% by weight of the marine animal product.” Fritsche et al. describes a feed composition containing 3.5% or 7% by weight of menhaden fish oil to be administered to pregnant sows. Thus, Fritsche et al. does not describe feeding a composition to pregnant sows wherein the composition as a final mixture comprises “about 0.025% to about 2% by weight of the marine animal product.” Accordingly, Fritsche et al. does not describe this necessary element of amended claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72 and, therefore, cannot anticipate these claims. Withdrawal of the rejection of amended claims 1-3, 5, 13, 15-17, 19-20, 23, 25, 41, and 71-72 under 35 U.S.C. § 102(b) is respectfully requested.

## **II. Applicants' claimed invention has met with great commercial success.**

If a product that embodies the invention supplants prior art products and is a great commercial success, then it can be inferred that the invention was not obvious because otherwise persons lured by the prospect of success would have developed the invention sooner. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 227 U.S.P.Q. 766 (Fed. Cir. 1985); *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 U.S.P.Q. 881 (Fed. Cir. 1985). Applicants submitted the declaration of Dr. Donald E. Orr, under 37 C.F.R. § 1.132, with the response filed on October 21, 2002. In the declaration, Dr. Donald E. Orr, the President and Chief Operating Officer of United Feeds, Inc., the assignee of the captioned patent application, describes in detail the great commercial success of the product that is used in Applicants' claimed method. The commercial success of the product that is used in the claimed method establishes that the claimed invention is nonobvious.

As Dr. Orr asserts in the § 1.132 declaration, the product (FERTILIUM™) that embodies the claimed method was introduced into the marketplace in February of 2002. FERTILIUM™ is an animal feed additive that contains marine animal products, and is fed to swine to increase the reproductive performance of swine. As asserted by Dr. Orr, approximately 150,000 sows are already being fed FERTILIUM™, and current market analysis projections predict that FERTILIUM™ will be fed to approximately 600,000 sows by 2003 and 1,000,000 sows by 2004. Approximately 130,000 pounds of FERTILIUM™ are currently being ordered per month from United Feeds, Inc., and, based on current market analysis projections, it is predicted that approximately 525,000 pounds per month will be ordered by 2003 and 875,000 pounds per month will be ordered by 2004.

As asserted in the § 1.132 declaration, the commercial acceptance of FERTILIUM™ is directly related to the claimed invention (*i.e.*, a method of increasing the reproductive performance of female swine by feeding the swine a composition comprising

marine animal products). The swine production business is very competitive and margins are very close. Swine producers have been impressed by the consistently good results obtained (*i.e.*, increased reproductive performance in swine) when swine are fed FERTILIUM™. The increased reproductive performance in swine results from the marine animal products that are a component of FERTILIUM™. Thus, the effectiveness of FERTILIUM™ in increasing reproductive performance of swine, as a result of the marine animal products in FERTILIUM™, has led to the commercial success of the composition used in the claimed method.

The commercial success of FERTILIUM™ is evidenced in the § 1.132 declaration by the detailed sales and usage figures presented in the declaration, and, as Dr. Orr asserts in the declaration, the commercial success of FERTILIUM™ has been more rapid than expected based on his experience in new product development in the animal feed supplement market. Furthermore, as Dr. Orr asserts in the § 1.132 declaration, FERTILIUM™ already has three to five times the market share that a flaxseed-containing product (the alternative), that was on the market for a number of years before FERTILIUM™ was introduced, has for use in increasing reproductive performance in female swine, and, as asserted in the declaration, FERTILIUM™ had only been on the market for about 8 months. Therefore, the great commercial success of FERTILIUM™, the product that embodies the claimed method, and the short time within which FERTILIUM™ has supplanted prior art products in the same market (*i.e.*, the flaxseed-containing product) indicate that the claimed invention is nonobvious because otherwise people lured by the prospect of commercial success would have developed the claimed invention sooner.

In the January 29, 2003 Office Action, the Examiner indicates that the declaration of Dr. Donald E. Orr is insufficient to establish that Applicants' invention has met with great commercial success because the declaration merely shows the value of sales (in

U.S. dollars) per the number of pounds sold in 2002 for FERTILIUM™ (see January 29 Office Action, page 9). The Examiner further indicates that a full market comparison with Applicants' competitors is required (see January 29 Office Action, page 9). The Examiner did not address the issue of the commercial success declaration in the June 2, 2003 Office Action so Applicants' arguments in reply to the Examiner's objections to the declaration are reiterated below.

Contrary to the Examiner's argument, MPEP § 716.03(b) entitled "Commercial Success Derived From Claimed Invention" contains a section entitled "Sales Figures Must Be Adequately Defined." This section reads in its entirety as follows:

Gross sales figures do not show commercial success *absent evidence as to market share*, *Cable Electric Products, Inc. v. Genmark, Inc.* 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, *Es parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988).

(Emphasis Added). Thus, the MPEP indicates that gross sales figures do not show commercial success absent evidence as to market share, citing *Cable Electric Products, Inc. v. Genmark, Inc.* Alternatively, gross sales figures in combination with the time period during which the product was sold could be shown or gross sales figures in combination with evidence as to what sales would normally be expected in the market could be provided.

In *Cable Electric Products, Inc. v. Genmark, Inc.*, 226 USPQ at 888, the court discussed the issue of the Plaintiff's commercial success declaration as evidence of nonobviousness and indicated that the Plaintiff had only provided information as to number of units of its product, a night light, sold and the profit per night light. The court stated that "[w]hat it shows in relation to commercial success is fairly minimal. Without further economic evidence, for example, it would be improper to infer that the reported sales represent a *substantial share of any definable market* or whether the profitability per unit is anything out of the ordinary in the industry involved." (Emphasis Added). *Id.* at 888. Thus,

the court in *Cable Electric Products, Inc. v. Genmark, Inc.* and the MPEP indicate that gross sales figures in combination with evidence as to market share is sufficient to demonstrate commercial success.

In the § 1.132 declaration, filed on October 21, 2002, in response to the April 23, 2002 Office Action, Dr. Donald E. Orr states:

FERTILIUM™ already has a market share that is three to five times greater than a flaxseed-containing product, and FERTILIUM™ has only been on the market for about 8 months. The flaxseed-containing product is an animal feed supplement containing ground flaxseed that is sold for use in increasing the reproductive performance of female swine, and the flaxseed-containing product had been on the market for a number of years before FERTILIUM™ was introduced to the marketplace. Therefore, FERTILIUM™, the product that embodies the claimed method, has met with great commercial success, and FERTILIUM™ has supplanted a flaxseed-containing product in the animal feed supplement market in the short time that FERTILIUM™ has been on the market.

Accordingly, Applicants provided evidence in the declaration of Dr. Donald E. Orr of the market share that FERTILIUM™ has attained in the short time that it has been on the market, and Applicants provided evidence that FERTILIUM™ supplanted the flaxseed-containing product (the alternative) in the animal feed supplement market after only 8 months on the market. This evidence satisfies both the requirements of MPEP § 716.03(b), and the case law cited in the MPEP. The Examiner indicates that a full market comparison with Applicants' competitors is required (see January 29 Office Action, page 9), but, respectfully, that is not what MPEP § 716.03(b) or the case law it cites requires, and it is unlikely that such a comparison could ever be done because it is doubtful that a competing business would divulge its market share, its monthly sales figures, or its profitability to its competitor, especially when that competitor has supplanted it in the industry.

### **III. Rejection of claims 4, 6, 8-11, 14, and 18 under 35 U.S.C. § 103(a).**

Claims 4, 6, 8-11, 14, and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fritsche et al. in view of Boudreux et al. The Examiner contends that these claims specify optimal parameters for Applicants' claimed method and that optimization is within the skill of the artisan. Claims 10-11 have been canceled without prejudice. Applicants respectfully traverse the Examiner's rejection. The invention of amended claims 4, 6, 8-9, 14, and 18 is not obvious over Fritsche et al. in view of Boudreux et al.

Amended claims 4, 6, 8-9, 14, and 18 are directed to "a method of increasing the reproductive performance of a female swine" by administering to the female swine a feed composition comprising marine animal products wherein the composition as a final mixture comprises about 0.025% to about 2% by weight of the marine animal product. Fritsche et al. describes a method of improving the health of nursing pigs (*e.g.*, by increasing immune function) by supplementing the diet of pregnant sows with 3.5% or 7% of menhaden fish oil. Fritsche et al. does not describe "a method of increasing the reproductive performance of a female swine" by supplementing a feed composition with marine animal products wherein the composition as a final mixture comprises about 0.025% to about 2% by weight of the marine animal product as claimed in claims 4, 6, 8-9, 14, and 18.

Moreover, as stated in Fritsche et al. in reference to feeding the pregnant sows a diet supplemented with lard (*i.e.*, control diet), menhaden fish oil, or a mixture of lard and menhaden fish oil, "the number of live pigs born per litter . . . birth weight . . . did not differ among treatment groups" (page 1843, column 1, paragraph 2). Thus, Fritsche et al. teaches that administering to pregnant sows a feed composition supplemented with 3.5% or 7% by weight of menhaden fish oil does not increase the number of live pigs born per litter or birth and weaning weights thereof. Accordingly, Fritsche et al. cannot render obvious "a method

of increasing the reproductive performance of a female swine" as claimed in claims 4, 6, 8-9, 14, and 18. In fact, Fritsche et al. teaches away from the claimed invention because Fritsche et al. teaches that administering to pregnant sows a feed composition supplemented with menhaden fish oil does not increase reproductive performances.

The Examiner rejected claims 4, 6, 8-11, 14, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Fritsche et al. in view of Boudreux et al. Boudreux et al. does nothing to overcome the insufficiencies of Fritsche et al. (discussed above) because Boudreux et al. does not describe "a method of increasing the reproductive performance of a female swine." Rather, Boudreux et al. describes the results of tests to determine the effects of omega-3 and omega-6 fatty acids on inflammation and thrombosis in dogs. Thus, Boudreux et al. does not overcome the insufficiencies of Fritsche et al. because Boudreux et al. does not describe "a method of increasing the reproductive performance of a female swine." Accordingly, the differences between the invention of claims 4, 6, 8-9, 14, and 18 and the cited references are such that the invention would not have been obvious in view of Fritsche et al. in combination with Boudreux et al. at the time the invention was made. Withdrawal of the rejection of amended claims 4, 6, 8-9, 14, and 18 under 35 U.S.C. § 103(a) is respectfully requested. Further, one skilled in the art would not utilize or expect Boudreux's disclosure would provide for any teaching to modify Fritsche for reproductive enhance purposes.

Furthermore, Applicants submitted in the response filed on October 21, 2002, the declaration under 37 C.F.R. § 1.132 of Dr. Donald E. Orr describing in detail the great commercial success of FERTILIUM™, the product that is the subject of Applicants' claimed method. A supplemental declaration is attached to show FERTILIUM™ meets the limitations of the claims. As discussed above, a flaxseed-containing product has been on the market as an animal feed additive for a number of years, and FERTILIUM™ has supplanted

the flaxseed-containing product in the short time that FERTILIUM™ has been on the market. Thus, the great commercial success of FERTILIUM™, the product that embodies Applicants' claimed method, establishes that the claimed invention is nonobvious because otherwise people lured by the prospect of commercial success would have developed the claimed invention sooner. Based on all of the above arguments, withdrawal of the rejection of amended claims 4, 6, 8-9, 14, and 18 under 35 U.S.C. § 103(a) is respectfully requested.

**IV. Rejection of claims 1-5, 14-16, 19-20, 23, 25, 41, and 71-72 under 35 U.S.C. § 103(a).**

Claims 1-5, 14-16, 19-20, 23, 25, 41, and 71-72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Abayasekara et al. As amended, each of claims 1-5, 14-16, 19-20, 23, 25, 41, and 71-72 specify that the feed composition as a final mixture comprises "about 0.025% to about 2% by weight of the marine animal product," a feature shown in Abayasekara." Thus, the subject matter of dependent claim 11 has been incorporated into each of claims 1-5, 14-16, 19-20, 23, 25, 41, and 71-72. The Examiner did not reject claim 11 over Abayasekara et al. Accordingly, withdrawal of the rejection of amended claims 1-5, 14-16, 19-20, 23, 25, 41, and 71-72 under 35 U.S.C. § 103(a) is respectfully requested.

At the interview of October 15, 2003, the Examiner felt the claims were too broad since the amount of omega fatty acids was not claimed and since the word comprising was open-ended. The Patent Laws allow for claiming as broad as the prior art limits and thus the broad nature of the claims is not an issue until prior art is disclosed that excuses the limiting of the claimed subject matter. The Examiner's attention was drawn to the fact that the commercial success did compare flaxseed the alternative and thus did show the appropriate comparison. The Examiner's interview summary appears to be a fair and complete summary of the interview.

**CONCLUSION**

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The amended claims are in condition for allowance. Applicants respectfully request allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



Mark M. Newman  
Registration No. 31,472  
(202) 289-1313